EXHIBIT H

2003 WL 22387568
— P.3d —
(Cite as: 2003 WL 22387568 (Utah))

Supreme Court of Utah.

Jeanne SCHAERRER, Plaintiff, Appellant, and Cross-Appellee,
v.
STEWART'S PLAZA PHARMACY, INC., Stewart Koeven, R.PH., Professional Compounding Centers of America, Inc., Jeffrey W. Johnson, M.D., American Home Products Corp., A.H. Robins Company, Inc., and Wyeth-Ayerst Laboratories Company, Inc., Defendants, Appellees, and Cross-Appellants.

No. 20010471.

Oct. 21, 2003.

Customer who began experiencing nausea, chest pains, and dizziness after taking diet drugs brought strict products liability action against pharmacy and pharmacist. The Fourth District Court, Provo Department, James R. Taylor, J., entered summary judgment for pharmacy and pharmacist, and customer appealed. The Supreme Court, Wilkins, J., held that: (1) pharmacists are exempt from strict products liability for failure to warn of the risks of prescription drugs; (2) pharmacy taking steps to improve compliance within a small group of patients in the local community it serves through legitimate marketing efforts and without violating state or federal regulations is not strictly liable as a manufacturer for the compounded drug product that it provides; and (3) pharmacist's actions were not that of drug manufacturer for purpose of strict products liability.

Affirmed.

[1] Appeal and Error ⚿863

30k863 Most Cited Cases

When reviewing a District Court's denial of summary judgment, Supreme Court grants no deference to the District Court's legal conclusions and reviews them for correctness.

[2] Products Liability ⚿46.2
313Ak46.2 Most Cited Cases

The unavoidably unsafe products doctrine shields manufacturers and sellers of prescription drugs from strict liability based on allegations of a design defect; however, doctrine does not extinguish strict liability claims based on manufacturing flaws or inadequate warnings. Restatement (Second) of Torts § 402A comment.

[3] Products Liability ⚿46.2
313Ak46.2 Most Cited Cases

Under "learned intermediary rule," manufacturers of prescription drugs have a duty to warn only the physician prescribing the drug, not the end user or patient; physician, after having received complete and appropriate warnings from the drug manufacturer, acts as learned intermediary between drug manufacturer and patient when preparing the drug prescription.

[4] Products Liability ⚿46.2
313Ak46.2 Most Cited Cases

A manufacturer of prescription drugs will be held directly liable to the patient for breach of the duty to make timely and adequate warnings to the medical profession of any dangerous side effects produced by its drug of which it knows or has reason to know.

[5] Products Liability ⚿46.2
313Ak46.2 Most Cited Cases

Learned intermediary rule providing that manufacturers of prescription drugs have a duty to warn only the physician prescribing the drug, not the end user or patient, must carry through to the pharmacist, as well, in order to serve its purpose fully, and thus, pharmacists are exempt from strict products liability for failure to warn of the risks of prescription drugs.

[6] Products Liability ⚿46.2
313Ak46.2 Most Cited Cases

So long as a pharmacist's ability to distribute prescription drugs is limited by the highly restricted, Food and Drug Administration (FDA)-regulated drug distribution system, and a pharmacist cannot supply a

patient with prescription drugs without an intervening physician's prescription, duty will not be imposed upon the pharmacist to warn of the risks associated with the use of prescription drugs.

[7] Products Liability 46.2
313Ak46.2 Most Cited Cases

Pharmacist's actions of consulting with physicians regarding compliance problems of their patients, designing new drug product, namely compounded one- a-day diet capsule, which was based on numerous prescriptions previously written by physicians and which was not otherwise available, and dispensing the new drug product directly to patients only after receipt of valid prescription orders were all legitimate activities for licensed pharmacist, and pharmacist's actions were not that of drug manufacturer for purpose of strict products liability.

[8] Products Liability 46.2
313Ak46.2 Most Cited Cases

So long as the pharmacy is acting within the rules and regulations set forth by the state and federal governments for the practice of pharmacy, providing compounded drug products to patients after receipt of a physician's prescription, and confining themselves to the traditional scope of pharmaceutical care, court need not shift the pharmacy into the category of drug manufacturer for the purpose of strict products liability.

[9] Products Liability 46.2
313Ak46.2 Most Cited Cases

For a pharmacy to cross the line and shift the pharmacy into the category of drug manufacturer for the purpose of strict products liability, there must be evidence of large-scale compounding activity, third party resale or wholesale distribution efforts, or other significant indicators of questionable and non-traditional pharmaceutical behavior.

[10] Products Liability 46.2
313Ak46.2 Most Cited Cases

A pharmacy taking steps to improve compliance within a small group of patients in the local community it serves through legitimate marketing efforts and without violating state or federal regulations is not strictly liable as a manufacturer for the compounded drug product that it provides.

[11] Products Liability 46.2
313Ak46.2 Most Cited Cases

The learned intermediary rule shields pharmacists from strict products liability so long as they are engaged in the practice of pharmacy and they properly fill a physician's prescription.

[12] Health 706
198Hk706 Most Cited Cases

Whether pharmaceutical practice is improper or excessive is a question of negligence, not strict liability, so long as the conduct occurs within the standard framework of pharmacists.

[12] Products Liability 46.2
313Ak46.2 Most Cited Cases

Whether pharmaceutical practice is improper or excessive is a question of negligence, not strict liability, so long as the conduct occurs within the standard framework of pharmacists.

[13] Health 706
198Hk706 Most Cited Cases

While pharmacists are exempt from strict products liability, a pharmacist may still be liable for claims of professional malpractice or negligence.

[13] Products Liability 46.2
313Ak46.2 Most Cited Cases

While pharmacists are exempt from strict products liability, a pharmacist may still be liable for claims of professional malpractice or negligence.

[14] Health 706
198Hk706 Most Cited Cases

Pharmacy could not be held liable in negligence for the harm consumer suffered as a result of taking the one-a-day diet tablet; although pharmacy compounded the tablet, consumer conceded at trial that no additional damage was suffered because of the compounding of the diet drugs, and without evidence of increased harm from pharmacy's activity, there could be no causation.

[14] Products Liability 46.2
313Ak46.2 Most Cited Cases

Pharmacy could not be held liable in negligence for

the harm consumer suffered as a result of taking the one-a-day diet tablet; although pharmacy compounded the tablet, consumer conceded at trial that no additional damage was suffered because of the compounding of the diet drugs, and without evidence of increased harm from pharmacy's activity, there could be no causation.

[15] Health 611
198Hk611 Most Cited Cases

A successful medical malpractice claim requires that the plaintiff prove the standard of care expected of the medical professional, breach, causation, and damages.

[16] Health 706
198Hk706 Most Cited Cases

Pharmacist has a generally recognized duty to possess and exercise the reasonable degree of skill, care, and knowledge that would be exercised by a reasonably prudent pharmacist in the same situation, and this duty is most commonly breached within the pharmacy profession by negligent packaging or dispensing of prescription drugs.

[16] Products Liability 46.2
313Ak46.2 Most Cited Cases

Pharmacist has a generally recognized duty to possess and exercise the reasonable degree of skill, care, and knowledge that would be exercised by a reasonably prudent pharmacist in the same situation, and this duty is most commonly breached within the pharmacy profession by negligent packaging or dispensing of prescription drugs.

[17] Health 706
198Hk706 Most Cited Cases

Breach of a pharmacist's duty can take the form of a misfilled prescription, dispensing a drug other than the one prescribed, giving an incorrect dosage, improper labeling or directions for use of the drug, or selling a prescription meant for one customer to another customer.

[17] Products Liability 46.2
313Ak46.2 Most Cited Cases

Breach of a pharmacist's duty can take the form of a misfilled prescription, dispensing a drug other than the one prescribed, giving an incorrect dosage, improper labeling or directions for use of the drug, or selling a prescription meant for one customer to another customer.

[18] Health 706
198Hk706 Most Cited Cases

Liability for negligence may be incurred if a pharmacist adds or substitutes an ingredient other than the one prescribed in a compounded drug or dispenses an incorrect percentage of ingredients in a compounded drug.

[18] Products Liability 46.2
313Ak46.2 Most Cited Cases

Liability for negligence may be incurred if a pharmacist adds or substitutes an ingredient other than the one prescribed in a compounded drug or dispenses an incorrect percentage of ingredients in a compounded drug.

[19] Health 706
198Hk706 Most Cited Cases

Although pharmacists can be held liable for negligence if there is a breach of duty, pharmacists are protected from claims if they fill a prescription precisely as directed by the manufacturer or physician.

[19] Products Liability 46.2
313Ak46.2 Most Cited Cases

Although pharmacists can be held liable for negligence if there is a breach of duty, pharmacists are protected from claims if they fill a prescription precisely as directed by the manufacturer or physician.

[20] Health 706
198Hk706 Most Cited Cases

Even in circumstances where a pharmacist has clearly breached his professional duty by negligently packaging or dispensing a prescription drug, a negligence claim will fail unless the plaintiff can prove the negligent behavior caused the injuries in question.

[20] Products Liability 46.2
313Ak46.2 Most Cited Cases

Even in circumstances where a pharmacist has clearly

breached his professional duty by negligently packaging or dispensing a prescription drug, a negligence claim will fail unless the plaintiff can prove the negligent behavior caused the injuries in question.

[21] Products Liability ⇐ 46.2
313Ak46.2 Most Cited Cases

Pharmacy collaborating with local physicians to develop a unique compounded product aimed at improving patient compliance and distributed according to prescription cannot be re-classified as a drug manufacturer and held strictly liable for the compounded drug product.

Charles F. Abbott, Scott Walker, Provo, and Richard M. Heimann, Richard M. Franco, Pierce Gore, San Francisco, CA, for plaintiff.

Michael P. Zaccheo, Rastlaan K. Coebergh, Salt Lake City, for defendants.

WILKINS, Justice:

*1 ¶ 1 Jeanne Schaerrer, plaintiff and appellant, appeals the district court's dismissal of her claims against Stewart's Plaza Pharmacy, Inc. and Stewart Koeven (collectively "Stewart's") for strict products liability. We affirm.

FACTUAL HISTORY

¶ 2 In June 1995, Schaerrer met with her physician, Dr. Jeffrey W. Johnson, who prescribed fenfluramine and phentermine as a weight loss measure. Schaerrer took fenfluramine and phentermine as prescribed from June 1995 through June 1997. She was originally prescribed twenty-milligram fenfluramine tablets to be taken three times daily and a generic phentermine capsule to be taken once daily. Schaerrer purchased her prescriptions from Woolsey's Pharmacy until October 1996.

¶ 3 Between November 1996 and June 1997, Schaerrer filled five prescriptions for fenfluramine and phentermine from Stewart's Plaza Pharmacy. Schaerrer switched pharmacies when a friend who worked at a doctor's office told her about a "one-a-day fen-phen" capsule available from Stewart's. Although he had never heard of a one-a-day fen-phen capsule, over the course of eight months Dr. Johnson wrote Schaerrer five prescriptions for sixty milligrams of fenfluramine and twenty milligrams of phentermine to be taken once daily. Dr. Johnson testified that he never independently investigated the one-a-day fen- phen capsule and that he assumed the pharmacy had determined the product's safety.

¶ 4 Stewart's began offering the one-a-day fen-phen capsule after Stewart Koeven, a pharmacist and the proprietor of the pharmacy, compounded raw fenfluramine manufactured by Professional Compounding Centers of America, Inc. ("PCCA"), phentermine powder manufactured by several pharmaceutical companies, methylcellulose as a time-release agent, and lactose as a filler. After creating his one-a-day fen-phen capsule, Koeven distributed samples of it to local physicians for experimental use with their patients. Eventually, Stewart's began receiving and filling prescriptions for the one-a-day fen-phen capsule. Koeven testified that neither he nor Stewart's Plaza Pharmacy ever tested the safety or efficacy of the compounded drug.

¶ 5 Schaerrer began experiencing nausea, chest pains, and dizziness in early 1997. She stopped taking fenfluramine and phentermine in mid-July 1997, and shortly after required open heart surgery to repair two damaged heart valves.

PROCEDURAL HISTORY

¶ 6 In December 1998, Schaerrer filed a complaint against several defendants: American Home Products Corporation (AHP) and other manufacturers of fenfluramine; Stewart's Pharmacy as the manufacturer of the one-a-day fen-phen capsule; Dr. Johnson, the prescribing physician; and PCCA as the pharmacy wholesaler that supplied the fenfluramine used in the one-a-day fen-phen capsule. Dr. Johnson was dismissed from the suit when his unopposed motion for summary judgment was granted in August 2000, and Schaerrer settled her claims against AHP in September 2000. Earlier, in February 2000, Schaerrer settled her claims against PCCA and signed a settlement agreement that is pertinent to this appeal. In that settlement agreement, Schaerrer agreed to waive recovery against any defendant who could successfully claim indemnity from PCCA. Specifically, Schaerrer agreed that:

> *2 to the extent that any party to the lawsuit or any other tort feasor, person, or entity obtains a final judgment against PCCA for contribution or indemnity for damage arising from the subject of this Lawsuit, Plaintiff waives her right to recover from said party, tort feasor, person, or entity any damages up to and including the total amount of the judgment against PCCA for indemnity.

¶ 7 Stewart's, the only remaining defendant, had filed its first motion for summary judgment in May 2000, arguing that Schaerrer had failed to offer any evidence to establish causation and that Stewart's, as a pharmacist, could not be held strictly liable for filling a physician's prescription. The trial court denied the motion, holding that a reasonable jury could find that Stewart's acted as a manufacturer rather than a pharmacist and could therefore be subject to strict liability. At Stewart's request, the trial court reconsidered the motion and granted partial summary judgment to Stewart's. The trial court found that Schaerrer had not presented evidence of causation that would sustain a negligence claim and that only a strict products liability claim remained against Stewart's. Schaerrer had stipulated on the record that she would not "seek to introduce evidence that Stewart's compounded capsule cause[d] increased risk of injury to her." Consequently, the trial court's order precluded Schaerrer from presenting evidence that Stewart's one-a-day fen-phen capsule, combining fenfluramine, phentermine, and a time-release agent in one dose, increased her risk of harm.

¶ 8 Stewart's filed a second motion for summary judgment in November 2000. It argued that since the only remaining claims against it were for strict products liability and Stewart's is entitled to indemnification from PCCA as an upstream manufacturer, Schaerrer's remaining claims should be dismissed under the terms of the PCCA settlement agreement because the agreement specifically stated that Schaerrer waived her right to recover from any party with the right to indemnification from PCCA. The trial court granted this motion and entered judgment dismissing Schaerrer's remaining claims against Stewart's.

¶ 9 Schaerrer appeals the trial court's ruling dismissing her claims against Stewart's on the basis of the indemnification clause of the PCCA settlement agreement. Schaerrer argues that the claims should not have been dismissed because the doctrine of implied indemnity was abrogated by the Utah Liability Reform Act of 1987 (ULRA). According to Schaerrer, Stewart's cannot claim indemnity from PCCA because the ULRA abrogated all claims for contribution or indemnity and instead relies on comparative fault principles to distribute loss among responsible parties in a single action. Furthermore, Schaerrer argues, even if the court chooses to preserve the right to claim implied indemnity under the ULRA, Stewart's is not entitled to indemnity in this case because Stewart's is a manufacturer, not a passive pharmacist. Because Stewart's independently compounded the one-a-day fen-phen capsule and marketed it to local physicians, Schaerrer argues that the pharmacy became an active manufacturer and forfeited its right to indemnification.

*3 ¶ 10 Stewart's argues in response that it cannot be held liable for the harm Schaerrer suffered because there is no evidence of causation to support a negligence claim and that, as a downstream link in the chain of distribution for fenfluramine, it is entitled to indemnification from PCCA. In response to Schaerrer's argument that the ULRA's comparative negligence scheme abrogated all claims for implied indemnity, Stewart's argues that there can be no chain of distribution liability without implied indemnity. The result of such a conclusion, argues Stewart's, is that both its claim for indemnity from PCCA and Schaerrer's claims of strict products liability against Stewart's would be eliminated. According to Stewart's, the claim against it only exists because it was a link in the chain of distribution of fenfluramine. Once the joint chain of distribution liability is eliminated and comparative fault applied, Stewart's can no longer be held liable for the damage done by fenfluramine, a defective product it merely sold rather than manufactured. According to Stewart's, Schaerrer's assertion that a jury could apportion fault among Stewart's and PCCA is incompatible with strict products liability principles.

¶ 11 Furthermore, Stewart's maintains, Schaerrer is incorrect in asserting that even if implied indemnification is retained by the court it should not apply in this case because Stewart's was an "active" link in the chain of distribution. Stewart's relies on the trial court's undisputed finding that Stewart's did nothing to alter the fenfluramine used in the one-a-day fen-phen capsule to support its assertion that there is no basis for a claim involving the type of "active" conduct that would preclude upstream indemnity.

¶ 12 Finally, Stewart's cross-appeals the trial court's denial of summary judgment in its favor based on the finding that Stewart's could be held liable as a manufacturer in a strict products liability suit. It asks the court to adopt a rule that would allow a pharmacist to engage in tangential manufacturing activities without incurring strict products liability. Stewart's asserts that drug compounding is accepted pharmaceutical practice and not manufacturing activity. Based on the stipulation that Stewart's actions in compounding the one-a-day fen-phen

capsule did not make the fenfluramine more dangerous, and their argument that it was simply following typical pharmaceutical practice, Stewart's claims it is a protected pharmacist, not a manufacturer. Because a pharmacist cannot dispense certain drugs without a valid physician's prescription, Stewart's maintains that a pharmacist should be immune from strict products liability suits.

¶ 13 Schaerrer, in response, urges the court to subject pharmacists to strict products liability claims if the pharmacist plays a manufacturing role. Schaerrer argues that Stewart's actions clearly went beyond those of a compounding pharmacist and that Stewart's effectively manufactured and marketed a new drug without abiding by FDA regulations.

ANALYSIS

I. STANDARD OF REVIEW

*4 [1] ¶ 14 Summary judgment is appropriate when there is no genuine issue as to any material fact and the moving party is entitled to judgment as a matter of law. Utah R. Civ. P. 56(c). When reviewing a district court's denial of summary judgment, we grant no deference to the district court's legal conclusions and review them for correctness. *Grynberg v. Questar Pipeline Co.*, 2003 UT 8, ¶ 20, 70 P.3d 1.

II. STEWART'S EXEMPTION FROM STRICT PRODUCTS LIABILITY

¶ 15 In this case, the essential question is whether the conduct of a professional pharmacist has transcended pharmaceutical practice and become that of a pharmaceutical drug manufacturer. Schaerrer argues that Stewart's acted as a manufacturer and should be strictly liable for the product it created. Stewart's argues in response: that as a manufacturer, it has a right of indemnity from PCCA that essentially negates Schaerrer's claims; that strict products liability does not apply to pharmacists; and that any pharmacist dispensing drugs according to a valid physician's prescription is governed by the applicable laws of negligence and professional misconduct, not the strict liability laws of product manufacturers and sellers. We first discuss our adoption of the learned intermediary rule, which exempts pharmacists from strict products liability, and then analyze whether the rule applies to Stewart's conduct in this case, concluding that Stewart's was acting as a compounding pharmacy and is exempt from strict products liability for the one- a-day fen-phen capsule under the facts of this case as presented on appeal.

A. Strict Products Liability and Comment K in Utah

¶ 16 This court expressly adopted the doctrine of strict products liability set forth in section 402A of the Restatement (Second) of Torts (1965) in *Hahn v. Armco Steel Co.*, 601 P.2d 152, 158 (Utah 1979). Section 402A reads:

> (1) One who sells any product in a defective condition unreasonably dangerous to the user or consumer or to his property is subject to liability for physical harm thereby caused to the ultimate user or consumer, or to his property, if (a) the seller is engaged in the business of selling such a product, and (b) it is expected to and does reach the user or consumer without substantial change in the condition in which it is sold.

Restatement (Second) of Torts § 402A (1965). We have since applied section 402A to require that in order to recover on strict liability against a seller, the plaintiff must prove (1) that a defect or defective condition of the product made it unreasonably dangerous, (2) that the defect was present at the time of the product's sale, and (3) that the defective condition was the cause of the plaintiff's injuries. *Interwest Constr. v. Palmer*, 923 P.2d 1350, 1356 (Utah 1996).

¶ 17 This court recognized an exception to strict liability for manufacturers and sellers of unavoidably unsafe products when it adopted the reasoning of comment k to section 402A in *Grundberg v. Upjohn Co.*, 813 P.2d 89 (Utah 1991). Comment k, known as the unavoidably unsafe products doctrine, recognizes that "[t]here are some products which, in the present state of human knowledge, are quite incapable of being made safe for their intended and ordinary use." *Id.* at 91 (quoting Restatement (Second) of Torts § 402A cmt. k (1965)). Such products, according to comment k, cannot subject a seller to strict liability for defects if prepared, distributed, and marketed properly and with appropriate directions and warnings.

*5 [2] ¶ 18 Based on this reasoning, we held in *Grundberg* that prescription drugs cannot, as a matter of law, be defective if approved by the United States Food and Drug Administration (FDA) and "properly prepared, compounded, packaged, and distributed." *Id.* at 90.

> We are persuaded that all prescription drugs should be classified as unavoidably dangerous in design because of their unique nature and value, the elaborate regulatory system overseen by the FDA, the difficulties of relying on individual lawsuits as

a forum in which to review a prescription drug's design, and the significant public policy considerations noted in *Brown* [concerning the financial and social costs of imposing strict liability].

Id. at 94. Thus, under Utah law, comment k shields manufacturers and sellers of prescription drugs from strict liability based on allegations of a design defect.

¶ 19 However, comment k does not extinguish strict liability claims based on manufacturing flaws or inadequate warnings. *Id.* at 92. Thus, this court protected manufacturers and sellers of prescription drugs from strict liability design defect claims while clearly assigning them the duty to warn of the risks associated with the use of their products.

B. The Learned Intermediary Rule and Pharmacist Liability

[3][4] ¶ 20 We next consider the learned intermediary rule. Under this rule, manufacturers of prescription drugs have a duty to warn only the physician prescribing the drug, not the end user or patient. *Lansdell v. Am. Home Prods. Corp.*, No. CV-99-S-2110-NE, 1999 WL 33548541, at *5, 1999 U.S. Dist. LEXIS 22540, at *14-*15 (N.D.Ala. Oct. 26, 1999). A manufacturer will be held directly liable to the patient for breach of the duty to make timely and adequate warnings to the medical profession of any dangerous side effects produced by its drug of which it knows or has reason to know. *Barson v. E.R. Squibb & Sons*, 682 P.2d 832, 835 (Utah 1984) (citing *McEwen v. Ortho Pharm. Corp.*, 270 Or. 375, 528 P.2d 522 (1974)). *The physician*, after having received complete and appropriate warnings from the drug manufacturer, *acts as a learned intermediary between the drug manufacturer and the patient* when preparing the drug prescription. It is the physician who is best situated to weigh the potential risks associated with a prescription drug against the possible benefits of the drug and the unique needs and susceptibilities of each patient. *Lansdell*, at *5. The physician thus has the ability to combine medical knowledge and training with an individualized understanding of the patient's needs, and is the best conduit for any warnings that are deemed necessary.

¶ 21 Many courts extend the learned intermediary rule to exempt pharmacists from strict products liability under a failure to warn theory. *See, e.g., Id.* at *5-6; *Kohl v. Am. Home Prods. Corp.*, 78 F.Supp.2d 885, 895-96 (W.D.Ark.1999); *Coyle v. Richardson-Merrell, Inc.*, 526 Pa. 208, 584 A.2d 1383, 1386-87 (1991); *McKee v. Am. Home Prods. Corp.*, 113 Wash.2d 701, 782 P.2d 1045, 1049-51 (1989). In *Coyle*, one of the seminal cases on the learned intermediary rule, the Pennsylvania Supreme Court noted that it would be "incongruous" to impose upon pharmacists a duty to warn patients directly when the manufacturer did not have a similar duty. 584 A.2d at 1386. Requiring a pharmacist to warn patients of the potential risks of a prescription drug would "have the effect of undermining the physician-patient relationship by engendering fear, doubt, and second-guessing." *Id.* Pharmacists might present patients with confusing or contradictory information, cast doubt on the propriety of a physician's legitimate exercise of sound medical judgment, or even refuse to fill valid prescriptions in an effort to avoid liability.

*6 [3][6] ¶ 22 Physicians are health care specialists, trained to act as "exclusive intermediaries" in the drug distribution system and obligated to provide appropriate medical care and supervision. Both manufacturers and pharmacists are limited in their ability to distribute FDA-regulated drugs because neither has direct access to the patient: Only through a physician's prescription may any prescription drug sale occur.

> Unlike the marketing system for most other products, the distribution system for prescription drugs is highly restricted. Pharmacists, as suppliers, do not freely choose which "products" they will make available to consumers in any given instance, and patients, as consumers, do not freely choose which "product" to buy. Physicians exercising sound medical judgment act as intermediaries in the chain of distribution, preempting, as it were, the exercise of discretion by the supplier-pharmacist, and, within limits, by the patient-consumer. With regard to the communication of warnings, we have recognized this as a real distinction that requires a different rule.

Id. We agree with the Pennsylvania Supreme Court that the learned intermediary rule must "carry through to the pharmacist as well" to serve its purpose fully. *Id.* We also recognize that this unique set of relationships necessitates adoption of the rule exempting pharmacists from strict products liability for failure to warn of the risks of prescription drugs. So long as a pharmacist's ability to distribute prescription drugs is limited by the highly restricted, FDA-regulated drug distribution system in this country, and a pharmacist cannot supply a patient with prescription drugs without an intervening physician's prescription, we will not impose a duty upon the pharmacist to warn of the risks associated with the use of prescription drugs.

C. Stewart's Conduct as a Pharmacy or Drug Manufacturer

¶ 23 We next address the pivotal question in this case: Does Stewart's conduct fall under the category of pharmacist or drug manufacturer? Schaerrer alleges that Stewart's has stepped outside the bounds of appropriate compounding pharmacist behavior through the following conduct: (1) creating a new drug product (2) prior to receipt of a valid prescription order for the product, (3) marketing the new product to local physicians, and (4) providing samples of the new product to local physicians for distribution to their patients. Since Stewart's cannot be strictly liable as a pharmacist, there must be sufficient evidence that Stewart's was no longer acting as a pharmacy, and instead had become a drug manufacturer when it created the one-a-day fen-phen capsule.

¶ 24 According to Stewart Koeven's testimony, he noticed that a number of the patients who filled their prescriptions for fenfluramine and phentermine at his pharmacy were not complying with their prescriptions. Specifically, according to Koeven, they were not taking all of the Pondim (fenfluramine) that their physicians prescribed. In approximately May of 1996, Koeven decided, based on his experience as a pharmacist with other time-release products, that a time- release version of the standard regime prescribed by physicians in the area might improve patient compliance. He contacted the physicians whose patients had been having compliance problems to determine whether they would be interested in the compounded drug product. The physicians expressed interest, and Koeven created sample capsules for some of the physicians to distribute to ten to twelve patients. Eventually, Koeven began receiving and filling prescription orders for his compounded one-a-day fen-phen capsules.

*7 ¶ 25 In Utah, the practice of pharmacy is defined by statute. According to section 58-17a-102(43) of the Utah Code, pharmaceutical practice includes "compounding, packaging, labeling, dispensing, administering, and the coincident distribution of prescription drugs and devices, provided that the administration of a prescription drug or device is ... pursuant to a lawful order of a practitioner when one is required by law; ... [and includes] providing pharmaceutical care." Utah Code Ann. § 58-17a-102(43)(b), (i) (2002).

> (a) "Pharmaceutical care" means carrying out the following in collaboration with a prescribing practitioner, and in accordance with division rule:
> (i) designing, implementing, and monitoring a therapeutic drug plan intended to achieve favorable outcomes related to a specific patient for the purpose of curing or preventing the patient's disease;
> (ii) eliminating or reducing a patient's symptoms; or
> (iii) arresting or slowing a disease process.
> (b) "Pharmaceutical care" does not include prescribing of drugs without consent of a prescribing practitioner.

Id. § 58-17a-102(29) (2002). Drug compounding is recognized as a traditional function of pharmaceutical practice and "is a process by which a pharmacist or doctor combines, mixes, or alters ingredients to create a medication tailored to the needs of an individual patient." *Thompson v. W. States Med. Ctr.*, 535 U.S. 357, 360, 122 S.Ct. 1497, 152 L.Ed.2d 563 (2002). Utah Code section 58-17a-102(6) defines prescription drug compounding as "the preparation, mixing, assembling, packaging, or labeling of reasonable quantities of a prescription drug ... by a licensed pharmacist," including "the preparation of a reasonable quantity of a prescription drug ... in anticipation of a valid prescription or medication order to be dispensed or administered to a patient based on routine, regularly observed prescribing patterns of a practitioner." Notably, the statute excludes from the definition of compounding the preparation of any prescription drugs "in a dosage form which is regularly and commonly available from a manufacturer in quantities and strengths prescribed by a practitioner." Utah Code Ann. § 58-17a-102(6)(d) (2002).

[7] ¶ 26 With these statutory definitions in mind, we observe that much of Stewart's conduct falls within the guidelines of acceptable pharmaceutical practice in Utah. Consulting with physicians regarding the compliance problems of their patients, designing a new drug product that is not otherwise available based on numerous prescriptions previously written by physicians, and dispensing the new drug product directly to patients only after receipt of a valid prescription order all appear to be legitimate activities for a licensed pharmacist. We find no statutory prohibition against such behavior, nor do the parties cite any authority on such a prohibition.

¶ 27 Marketing efforts are not addressed directly in the statutes, except as they may qualify as "collaboration" between a pharmacist and physician, but a recent United States Supreme Court case guides us in our analysis. In *Thompson v. Western States*

Medical Center, the Court determined that Congress may not prohibit pharmacists from soliciting prescription orders or advertising or promoting "the compounding of any particular drug, class of drug, or type of drug." 535 U.S. 357, 365, 377, 122 S.Ct. 1497, 152 L.Ed.2d 563 (2002). In the early 1990s the FDA promulgated an interpretive rule or policy statement concerning the "large-scale speculative 'compounding' " of some pharmacies that appeared to be overstepping the bounds of traditional pharmaceutical practice. *Profls & Patients for Customized Care v. Shalala*, 56 F.3d 592, 593, 594 (5th Cir.1995). In the Food and Drug Administration Modernization Act of 1997 (FDAMA), Congress enacted some of the FDA's policies through its requirements for exemption of pharmacy-compounded drugs from the new drug approval process. *Thompson*, 535 U.S. at 364, 122 S.Ct. 1497. A group of pharmacies that specialize in drug compounding challenged two of the FDAMA's requirements for exemption as violations of their First Amendment right to free speech: (1) that prescriptions for compounded drugs be unsolicited and (2) that advertising or promoting "the compounding of any particular drug, class of drug, or type of drug" be prohibited. The Supreme Court struck down these two speech-related provisions as unconstitutional. In light of this decision, we find it difficult to endorse an argument for subjecting a pharmacy to strict products liability as a manufacturer based upon the pharmacy's exercise of constitutionally protected commercial speech.

*8 ¶ 28 For over ten years, the FDA has expressed concern that increasing numbers of pharmacies are engaged in manufacturing behavior "that is clearly outside the bounds of traditional pharmacy practice." FDA Office of Regulatory Affairs, Compliance Policy Guide Section 460.200 (May 2002). The FDA's most recent policy statement governing review of compounding pharmacies, issued after the *Thompson* decision, presents nine acts which it deems provocative:

1. Compounding of drugs in anticipation of receiving prescriptions, except in very limited quantities in relation to the amounts of drugs compounded after receiving valid prescriptions.
2. Compounding drugs that were withdrawn or removed from the market for safety reasons....
3. Compounding finished drugs from bulk active ingredients that are not components of FDA-approved drugs.
4. Receiving, storing, or using drug substances without first obtaining written assurance from the supplier that each lot has been made in an FDA-registered facility.
5. Receiving, storing, or using drug components not guaranteed to meet official compendia requirements.
6. Using commercial scale manufacturing or testing equipment for compounding drug products.
7. Compounding drugs for third parties who resell to individual patients or offering compounded drug products at wholesale to other state licensed persons or other commercial entities for resale.
8. Compounding drug products that are commercially available in the marketplace or that are essentially copies of commercially available FDA-approved drug products....
9. Failing to operate in conformance with applicable state law regulating the practice of pharmacy.

Id. While the policy statements of the FDA are by no means binding on this court, they do provide meaningful guidance on a question that few, if any, courts in this country have yet considered.

¶ 29 According to the facts alleged in this case, Stewart's only act that might have run afoul of these prohibitions is the first--that no compounding occur in advance of a prescription except in limited quantities in relation to future prescriptions. Since the record before us does not disclose the exact quantities of the one-a-day fen-phen capsules that Stewart's compounded in advance of any prescription, nor how many prescriptions were received after advertising the one-a-day fen-phen, it is possible that the ratio would raise warning flags. However, it is clear that the FDA does not see all pre- prescription compounding as clearly indicative of manufacturing behavior, nor do we. Some pre-prescription compounding activity is appropriate, particularly if the purpose and scale of the activity is in line with the traditional role that pharmacies play in the health care process.

¶ 30 In *Thompson*, the Court noted that the government must be able to distinguish between "small-scale compounding and large-scale drug manufacturing" to preserve "the effectiveness and integrity of the FDCA's new drug approval process" while maintaining the availability of specially compounded drugs for those patients who need them. 535 U.S. at 369-70, 122 S.Ct. 1497. Clearly, according to the Court and the policy statements of the FDA, the size and scale of a pharmacy's compounding practice is one of the most important indicators of improper "manufacturing" conduct. In this case, we have no evidence of the overall scope of Stewart's practice, nor of the proportion of that

practice committed to compounding the one-a-day fen-phen. All we know is that some of Stewart's clients had compliance problems, and that at least seven physicians began prescribing the one-a-day fen-phen after it was developed. There is no indication from the record that Stewart's was conducting a large-scale, speculative, compounding business similar to that of a commercial pharmaceutical drug manufacturer. Nor was Stewart's using commercial scale equipment, compounding drugs for resale or wholesale distribution, or, as Schaerrer emphasizes, compounding a drug already available in the marketplace. Finally, there are no allegations that Stewart's violated any state or federal regulations governing the use of FDA-regulated drugs or the practice of pharmacy.

*9 ¶ 31 We do find the distribution of sample one-a-day fen-phen capsules to local physicians problematic, and perhaps indicative of the type of marketing used by large-scale drug manufacturers. However, the parties have provided no authority, nor do we find any, for the proposition that pharmacies must limit their advertising efforts to written materials and other strategies that do not include limited distribution of product samples. The fact remains that the pharmacy did not distribute the samples directly to patients, and cannot profit from any sale of one-a-day fen-phen without a valid prescription. The physician remains a gatekeeper between the compounded drug and the patient, and continues to control the patient's access to all prescription drugs.

[8] ¶ 32 Furthermore, strict liability for manufacturers exists in large part as a deterrent and a method of allocating the risk of loss among those best equipped to deal with it. Compounding pharmacies provide a unique and valuable service in our health care system, one which we have no reason to deter at this point. Nor do we believe that pharmacies are in a good position to insure against, or take steps to reduce the risk of, harm done by the drugs used in their compounded products through additional warnings. So long as the pharmacy is acting within the rules and regulations set forth by the state and federal governments for the practice of pharmacy, providing compounded drug products to patients after receipt of a physician's prescription, and confining themselves to the traditional scope of pharmaceutical care, we need not shift the pharmacy into the category of drug manufacturer for the purpose of strict products liability.

[9][10][11][12] ¶ 33 The conduct alleged in this case is not that of a drug manufacturer. Everything that Stewart's did was in the context of a compounding pharmacist. Stewart's may have overstepped the bounds of appropriate pre-prescription compounding or marketing activity, but that question is best reserved for state and federal regulators. For a pharmacy to cross the line and become a manufacturer, there must be evidence of large-scale compounding activity, third party resale or wholesale distribution efforts, or other significant indicators of questionable and non-traditional pharmaceutical behavior. A pharmacy taking steps to improve compliance within a small group of patients in the local community it serves through legitimate marketing efforts and without violating state or federal regulations is not strictly liable as a manufacturer for the compounded drug product that it provides. The learned intermediary rule shields pharmacists from strict products liability so long as they are engaged in the practice of pharmacy. Whether their pharmaceutical practice is improper or excessive is a question of negligence, not strict liability, so long as the conduct occurs within the standard framework of pharmacists.

III. PHARMACIST LIABILITY IN UTAH

[13][14] ¶ 34 The only remaining grounds for a claim against Stewart's in this case is negligence. While pharmacists are exempt from strict products liability in Utah, a pharmacist may still be liable for claims of professional malpractice or negligence. However, Schaerrer disposed of any claim for malpractice or negligence when she stipulated that the one-a-day fen-phen did not increase her risk of harm.

*10 [15][16][17][18][19] ¶ 35 A successful medical malpractice claim requires that the plaintiff prove the standard of care expected of the medical professional, breach, causation, and damages. *Robb v. Anderton*, 863 P.2d 1322, 1327 (Utah Ct.App.1993). Specifically, a pharmacist has a generally recognized duty to "possess and exercise the reasonable degree of skill, care, and knowledge that would be exercised by a reasonably prudent pharmacist in the same situation." Marjorie A. Shields, Annotation, *Exemplary or Punitive Damages for Pharmacist's Wrongful Conduct in Preparing or Dispensing Medical Prescription--Cases not Under Consumer Product Safety Act*, 109 A.L.R.5th 397, § 2 (2003). This duty is most commonly breached within the pharmacy profession by negligent packaging or dispensing of prescription drugs. For example, breach of a pharmacist's duty can take the form of a misfilled

prescription, dispensing a drug other than the one prescribed, giving an incorrect dosage, improper labeling or directions for use of the drug, or selling a prescription meant for one customer to another customer. Timothy E. Travers, Annotation, *Druggist's Civil Liability for Injuries Sustained as a Result of Negligence in Incorrectly Filling Drug Prescriptions*, 3 A.L.R.4th 270 (1981). Liability for negligence may also be incurred if a pharmacist adds or substitutes an ingredient other than the one prescribed in a compounded drug or dispenses an incorrect percentage of ingredients in a compounded drug. *Id.* Although pharmacists can be held liable for negligence if there is a breach of duty, pharmacists are protected from claims if they fill a prescription precisely as directed by the manufacturer or physician. *Elliott v. A.H. Robins Co.*, 262 A.D.2d 132, 691 N.Y.S.2d 501, 502 (App.Div.1999).

[20] ¶ 36 Even in circumstances where a pharmacist has clearly breached his professional duty by negligently packaging or dispensing a prescription drug, a negligence claim will fail unless the plaintiff can prove the negligent behavior caused the injuries in question. In the current case, Stewart's cannot be held liable for the harm Schaerrer suffered as a result of taking the one-a- day fen-phen tablet. Although Stewart's compounded the tablet, Schaerrer conceded at trial that no additional damage was suffered because of the compounding of the fenfluramine and phentermine. Without evidence of increased harm from Stewart's activity, there can be no causation. As a result of the Schaerrer stipulation that Stewart's compounding was not a proximate cause of the damage she suffered, Schaerrer cannot make out a complete negligence claim and therefore has no recourse against the pharmacy.

CONCLUSION

[21] ¶ 37 We affirm the district court's decision to dismiss Schaerrer's claims, although on different grounds. We extend the learned intermediary rule to exempt pharmacies from strict products liability when they properly fill a physician's prescription. We hold that a pharmacy collaborating with local physicians to develop a unique compounded product aimed at improving patient compliance and distributed according to prescription cannot be re-classified as a drug manufacturer and held strictly liable for the compounded drug product. Finally, we note that the only basis for a claim against Stewart's is in negligence, which Schaerrer cannot allege in the absence of evidence of causation. The district court's dismissal of the case is affirmed.

*11 ¶ 38 Chief Justice DURHAM, Associate Chief Justice DURRANT, Justice PARRISH, and Judge NEHRING concur in Justice WILKINS' opinion.

¶ 39 Justice RUSSON did not participate herein; District Judge RONALD E. NEHRING sat.

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